

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 1, 2, 4, 6 and 8 are currently pending in the present application. The Office Action is non-final. Claims 1, 2, 4 and 8 have been amended and claims 3, 7 and 9 cancelled without prejudice or disclaimer of the subject matter contained therein. No new matter has been added by way of the amendments. For instance, claim 1 has been amended to include textual subject matter taken from claims 7 and 9, now cancelled. Additional support for claim 1 can be found at page 14, lines 8-14 of the present specification. Claim 2 has been amended to include textual subject matter taken from claim 3, now cancelled. Additional support for claim 2 can be found at page 10, lines 4-24 of the present specification. Claim 4 was amended to depend from claims 1 or 2. Claim 8 was amended to depend from claim 1. Thus, no new matter has been added.

Based upon the above considerations, entry of the present Amendment is respectfully requested.

Issues Under 35 U.S.C §112, First Paragraph, Written Description

Claims 1-4 and 6-9 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter not described in the specification in such a way as to reasonably convey to

one skilled in the art that the inventor was in possession of the claimed invention at the time the application was filed (See Office Action dated September 22, 2008 at page 2; hereinafter "Office Action"). Applicants respectfully traverse.

Applicants have cancelled claims 3, 7 and 9, without prejudice or disclaimer of the subject matter contained therein, thus obviating the present rejections as to these claims. Applicants respectfully traverse the rejections as to the remaining claims.

Although Applicants do not agree with the Examiner's assertions, in order to advance prosecution, Applicants have amended claim 1, without prejudice or disclaimer of the subject matter contained therein, to incorporate the textual subject matter claims 7 and 9, now cancelled. Additional support for claim 1 can be found at page 14, lines 8-14 of the present specification. Also, claim 2 has been amended, without prejudice or disclaimer of the subject matter contained therein, to incorporate the textual subject matter of claim 3, now cancelled. Additional support for claim 2 can be found at page 10, lines 4-24 of the present specification.

Further, Applicants have amended claim 1 to "first" and "second" granule and amended claim 2 to "first" granule in order to describe each of the granules without a functional term.

The amendments further describe that the first granule is a proton pump inhibitor, and that the second granule is the composition from claim 9. Applicants submit that the claims contain subject matter adequately described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor was in possession of the claimed invention. Applicants also submit that the amended claims resolve the above rejection since each granule is distinct and can be found within the specification without confusion.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

Issues Under 35 U.S.C. § 112, Second Paragraph, Indefiniteness

Claims 1-4 and 6-9 stand rejected twice in separate rejections under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner asserts in two separate rejections that the above claims are indefinite (See the Office Action at pages 4-6).

Applicants have cancelled claims 3, 7 and 9, without prejudice or disclaimer of the subject matter contained therein, thus obviating the present rejections as to these claims. Applicants respectfully traverse the rejections as to the remaining claims.

Although Applicants do not agree with the Examiner's assertions, in order to advance prosecution, Applicants have amended claim 1, without prejudice or disclaimer of the subject matter contained therein, to incorporate the textual subject matter claims 7 and 9, now cancelled. Also, claim 2 has been amended, without prejudice or disclaimer of the subject matter contained therein, to incorporate the textual subject matter of claim 3, now cancelled. As indicated in the previous rejection, Applicants submit that the presently amended claims further define the first granule as a proton pump inhibitor, and the second granule as the composition from claim 9, which avoids confusion within the claims.

Also, claim 1 was amended to incorporate thickening agents that are disclosed on page 14 of the specification as a Markush group. Additionally, Applicants amended the claims to provide within Markush groups specific polymers for each of the functional polymers, which can be found on page 10 of the specification. Although HPMC and HPC may have a dual use as either as a thickener or functional polymer, Applicants respectfully submit that the claims specifically

point out the role for each of these chemicals and that the amendments adequately define each of the components within the claims. Applicants submit that the presently amended claims particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

Issues Under 35 U.S.C. § 102(b), Anticipation

The Examiner has cited the following rejections under 35 U.S.C. § 102(b) below.

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by **Depui *et al.***, WO 97/25066 (hereinafter “**Depui**”).

The Examiner asserts that all the critical elements of the present invention are taught by Depui (See the Office Action at pages 6-8).

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by **Ukai *et al.***, U.S. Patent Application No. 2002/0039597 (hereinafter “**Ukai**”).

As in the above rejection, The Examiner asserts that all the critical elements of the present invention are taught by Ukai. (See the Office Action at pages 8-10).

Applicants have cancelled claims 3 and 7, without prejudice or disclaimer of the subject matter contained therein, thus obviating the present rejections as to these claims. Applicants respectfully traverse the above rejections as to the remaining claims.

Legal Standard for Determining Anticipation

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.” *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) “The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, *i.e.*, identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Although Applicants do not agree with the Examiner's assertions, in order to advance prosecution, Applicants have amended claim 1, without prejudice or disclaimer of the subject matter contained therein, to incorporate the textual subject matter of non-rejected claim 9, now cancelled. Since Depui is silent regarding the incorporation of light anhydrous silicic acid and Ukai is silent regarding the incorporation of light anhydrous silicic acid or citric acid, the cited references do not teach the present invention.

In light of the above, the cited Depui and Ukai references cannot be a basis for a rejection under § 102(b).

Applicants respectfully request reconsideration and withdrawal of the present rejection.

Issues Under 35 U.S.C. § 103(a), Obviousness

The Examiner has cited the following rejections under 35 U.S.C. § 103(a) below.

Claim 9 stands rejected under 35 U.S.C. § 103(a) as obvious over Depui, as applied to claims 1-4 and 6-8, in view of **Pharmaceutical Dosage Forms: Tablets** (Volume 1, second edition; hereinafter “**PDFT**”). The Examiner asserts that the above claim is obvious in light of the combination of the above references (See the Office Action at pages 10-12).

Claim 9 stands rejected under 35 U.S.C. § 103(a) as obvious over Ukai, as applied to claims 1-4 and 6-8, in view of **PDFT** and **Samejima et al.**, U.S. Patent No. 5,068,112 (hereinafter “**Samejima**”). The Examiner also asserts that claim 9 is obvious in light of the combination of the above references (See the Office Action at pages 13-15).

Applicants have cancelled claims 3 and 7, without prejudice or disclaimer of the subject matter contained therein, thus obviating the present rejections as they apply to these claims. Applicants respectfully traverse the above rejections as they apply to the remaining claims.

Applicants have cancelled claim 9, without prejudice or disclaimer of the subject matter contained therein, thus obviating the present rejections with regard to claim 9. However, in as much as the rejection may be applied to amended claim 1, which incorporates the textual subject matter of claim 9 herein, Applicants respectfully traverse the rejection and submit the following remarks.

Legal Standard for Determining Prima Facie Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.).

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit

showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

The Supreme Court of the United States has recently held that the teaching, suggestion, motivation test is a valid test for obviousness, but one which cannot be too rigidly applied. See *KSR Int'l Co. v. Teleflex Inc.*, 127 SCt 1727, 82 USPQ2d 1385 (U.S. 2007). The Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, *ibid.*, reaffirmed the Graham factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquiries under Graham are:

- (a) determining the scope and contents of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (U.S. 1966).

The Court in *KSR Int'l Co. v. Teleflex, Inc.*, *supra.*, did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

Even so, the Court in *KSR Int'l Co. v. Teleflex, Inc.*, *ibid.*, rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

Accordingly, while the courts have adopted a more flexible teaching, suggestion, motivation (TSM) test in connection with the obviousness standard based on the *KSR v. Teleflex* case, which case involved a mechanical device in a relatively predictable technological area, it remains true that, despite this altered standard, the courts recognize inventors face additional barriers in relatively unpredictable technological areas as noted in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

Further, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336, quoted with approval in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. But before the Examiner can utilize these guidelines, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*; *supra*. To reject a claim based on the above mentioned guidelines, the Examiner must resolve the *Graham* factual inquiries. MPEP §2143.

If the Examiner resolves the *Graham* factual inquiries, then the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. §§ 2141 and 2143 set forth the rationales that were established in *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Exemplary rationales are set forth in MPEP §§ 2141 and 2143 that may support a conclusion of obviousness, and include:

(a) combining prior art elements according to known methods to yield predictable results;

(b) simple substitution of one known element for another to obtain predictable results;

(c) use of known technique to improve similar devices (methods, or products) in the same way;

(d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(e) "obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success

(f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Additionally, MPEP § 2143.03 clearly directs that all claim limitations must be considered in view of the cited prior art in order to establish a prima facie case of obviousness.

Applicants respectfully submit that the Examiner has not appropriately resolved the *Graham* factors, including the factors of determining the scope and content of the prior art and ascertaining the differences between the prior art and the claims that are at issue. Based on the following, Applicants maintain that the above mentioned *Graham* factors actually reside in

Applicants' favor. Additionally, Applicants submit that since the Examiner did not properly resolve the *Graham* factors, the rationale the Examiner provides for combining the cited references is improper.

Applicants respectfully submit that the present invention is distinct from the cited references.

Distinctions Over the Cited Art

As previously indicated, Applicants have amended claim 1, without prejudice or disclaimer of the subject matter contained therein, to incorporate the textual subject matter claims 7 and 9, now cancelled. Also, claim 2 has been amended, without prejudice or disclaimer of the subject matter contained therein, to incorporate the textual subject matter of claim 3, now cancelled.

In the claimed invention, mannitol is contained in the second granule. Also, when mannitol is used as an active component (*i.e.*, the first granule), it is required to contain about 100 g of mannitol for a diuretic and contain 20 g or more of mannitol for a laxative. Such amounts in a diuretic and a laxative are disclosed in Exhibit 1 for intravenous administration (See Exhibit 1: Mannitol, Drug Information Provided by Lexicomp Merck, pages 4 to 5) and Exhibit 2 (See Exhibit 2: Wikipedia- Mannitol, page 2) for oral administration, respectively. For a formed preparation containing mannitol, it is required to contain at the most about 1 g of mannitol, as disclosed in Exhibit 3 (See Exhibit 3: U.S. FDA, Center for Drug Evaluation and Research, "Inactive Ingredient Search for Approved Drug Products, Search Results for:

Mannitol, pages 3 to 4). Applicants have herein provided Exhibits 1-3 for the Examiner's consideration.

Applicants submit that due to the above, mannitol is not an active component (*i.e.*, the first granule) but is a second granule that is an extender for the first granule in the present invention.

Additionally, the amended claim 2 refers to the functional polymer which is a gastric polymer, an enteric polymer or a sustained release polymer, limited to the species provided within the claim. The hereby defined functional polymer has plural functions. Applicants submit that based on the claims, the specific functional polymer is different from the thickening agent of amended claim 1 at this point. The thickening agent of amended claim 1 is also limited to species disclosed.

The primary reference Depui is silent with regards to the second granule containing an active component.

Also, the other primary reference Ukai uses a material for a seed in examples of wet granulation, dry granulation and tablets. Such a reference disclosure will not show, nor suggest, coating of a pharmacologically active component on the seed. The latter will form a different preparation in structure than disclosed in former.

Additionally, in both wet granulation and dry granulation, a plurality of components are mixed and uniformly dispersed in the resulting granules. In granulation with a seed, components are displaced separately in layers.

Based on a full review of the presently amended claims, and the arguments above, Applicants believe that there are distinctions between the present invention and the cited primary

references Depui and Ukai. Therefore, the addition of PDFT with Depui or the addition of PDFT and Samejima to Ukai fail to resolve the deficiencies of the cited primary references. It is also noted that neither of the cited primary prior art references (*i.e.*, Depui nor Ukai) provide any teaching or disclosure that would allow one of ordinary skill in the art to arrive at the instant invention as claimed. More particularly, one of ordinary skill in the art, upon considering the disclosures of each of Depui and Ukai, would find no reason or rationale in the cited art to arrive at the instant invention as claimed. As such, it follows that neither of the cited art references' disclosures can serve as a proper basis for rejecting any of instantly pending claims 1, 2, 4, 6 and 8 under the provisions of 35 U.S.C. § 103(a). Any contentions of the USPTO to the contrary must be reconsidered at present.

In light of the cited case law above, the lack of disclosure of all features as instantly claimed, the rejection in view of Depui with PDFT and the rejection in view of Ukai, PDFT and Samejima are overcome and/or rendered moot.

Applicants respectfully request reconsideration and withdrawal of the present rejections.

CONCLUSION

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters within the present application that need to be resolved, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: **DEC 22 2008**

Respectfully submitted,

By 

John W. Bailey
Registration No.: 32,881
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicants

Attachments: Exhibit 1: Mannitol, Drug Information Provided by Lexicomp Merck, pages 4-5.

Exhibit 2: Wikipedia- Mannitol, page 2.

Exhibit 3: U.S. FDA, Center for Drug Evaluation and Research, "Inactive Ingredient Search for Approved Drug Products, Search Results for: Mannitol," pages 3 to 4.